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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,250	10/24/2003	Gene DiPoto	ENDIUS.032A	1390

20995 7590 03/08/2007  
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EXAMINER
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MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/08/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/08/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

Application No.

10/693,250

Applicant(s)

DIPOTO, GENE

Examiner

Michael G. Mendoza

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 22-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 19-21 is/are rejected.
- 7) ☒ Claim(s) 14-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/29/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. 5800549 in view of Davison 6530926.

3. Bao et al. teaches a method of replacing a portion of disc of a patient, the disc having an annulus and a nucleus, comprising: advancing an annulotomy tool through an access device to the intervertebral space; forming an aperture in the annulus; advancing a disc evacuation tool through the access device and through the aperture; removing at least a portion of the nucleus through the access device to at least partially evacuate the intervertebral space; and delivering a replacement disc nucleus into the partially evacuated intervertebral space through the access device (col. 6, lines 3-18). It should be noted that Bao et al. fails to teach the access device being inserted in a first configuration having a first cross-section area at a distal portion thereof; and configuring the access device such that the distal portion thereof is enlarged from the first configuration to a second configuration wherein the distal portion extend across at least a portion of the disc.

4. Davison teaches a method that uses a common access having a first configuration and a second configuration for enhanced viewing of a surgical site.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the access device of Davison with the method steps taught by Bao et al. to give the surgeon performing the surgery an expanded surgery site for viewing (col. 5, lines 30-37).

5. Boa/Davison teaches the method of claim 1, wherein the replacement disc nucleus comprises an injectable material; wherein the injectable material is chosen from a group comprising: hydrogels, thermoplastic elastomers, and proteinaceous biopolymers; wherein the replacement disc nucleus an expandable element (col. 5, lines 19-23).

6. Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boa/Davison as applied to claim 1-4 above, and further in view of Bao et al. 7001431.

7. Boa/Davison teaches the method of claim 4. It should be noted that Boa/Davison fails to teach wherein the expandable element comprises: a bag in a collapsed configuration, wherein the bag may be inflated or allowed to expand.

8. Bao et al. teaches a method of replacing a spinal disc that uses a common bag (fig. 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the bag of Bao et al. as an alternative to the elastomeric replacement disc of Boa/Davison since the bag of Bao et al. is a mechanic expedient of the replacement disc of Boa/Davison.

9. Bao/Davison/Bao teaches the method of claim 5, wherein the replacement disc nucleus further comprises a biocompatible material, which is injected into the bag in an expanded configuration; wherein the bag can be inflated to an expanded configuration

with a gas or liquid after insertion; wherein a tool is inserted through the access device in order to inflate the bag (fig. 5); wherein the bag comprises a self-expanding frame that assumes a collapsed state for insertion, and an expanded state once inserted; wherein the self-expanding frame is composed of a shape-memory material (col. 11, lines 18-29).

10. Claims 11-13, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao/Davison/Bao as applied to claims 5-10 above, and further in view of Ferree 6969404.

11. Bao/Davison/Bao teaches the method of claim 6. It should be noted that Bao/Davison/Bao fails to teach wherein the biocompatible material includes tissues, cells, or extracellular matrix components.

12. Ferree teaches a method for filling disc space using tissues, cells, or extracellular matrix components (col. 2, lines 50-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the tissues, cells, or extracellular matrix components of Ferree as an alternative to the hydrogel of Bao/Davison/Bao since the hydrogel of Bao/Davison/Bao is a mechanic expedient of the the tissues, cells, or extracellular matrix components of Ferree.

13. Bao/Davison/Bao/Ferree teaches the method of claim 6, wherein the biocompatible material includes autograft nucleus pulposus, allograft nucleus pulposus or xenograft nucleus pulposus; wherein the biocompatible material includes morselized nucleus or annulus from the disc (col. 2, lines 50-55).

***Allowable Subject Matter***

14. Claims 14-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MM



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SUPERVISORY PATENT EXAMINER